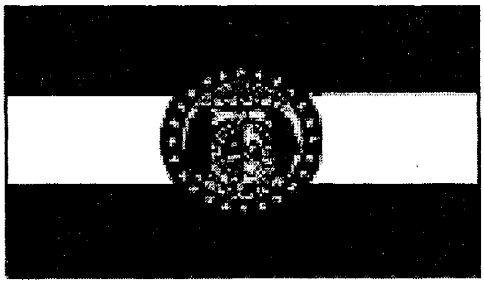
A GUIDE TO PRESCRIBING, ADMINISTERING AND DISPENSING

CONTROLLED SUBSTANCES IN MISSOURI



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PREPARED AND DISTRIBUTED BY THE MISSOURI TASK FORCE ON MISUSE, ABUSE AND DIVERSION OF PRESCRIPTION DRUGS

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Missouri Board of Pharmacy
Missouri Dental Board
Missouri State Board of Nursing
Missouri State Board of Optometry
Missouri State Board of Podiatric Medicine
Missouri Veterinary Medical Board
Missouri State Board of Registration for the Healing Arts
Missouri Bureau of Narcotics and Dangerous Drugs
Office of the Missouri Attorney General
Missouri Association of Osteopathic Physicians and Surgeons
Missouri Dental Association
Missouri Hospital Association
Missouri Nurses Association
Missouri Optometric Association
Missouri Pharmacy Association
Missouri State Medical Association
Physicians' Health Program (MAOPS)
Missouri Physicians' Health Program (MSMA)
Missouri Veterinary Medical Association
Drug Enforcement Administration
Missouri League for Nursing

The abuse of prescription drugs is a serious social and health problem in the United States. As a practitioner, you share responsibility for preventing prescription drug abuse and diversion. Prescribing controlled substance medications is always a balancing act; the physician must do his or her best to safely and effectively treat their patients while at the same time avoid prescription practices that could potentially foster drug misuse or abuse. The information provided in this booklet is intended to aid physicians and other health professionals in their practice.

- You have a legal and ethical responsibility to uphold the law and to help protect society from drug abuse.

- Protect your practice from becoming an easy target for drug diversion and remember that you have a legal responsibility to acquaint yourself with the state and federal requirements for the prescribing and dispensing of controlled substances. Should you fail to abide by the requirements, you are subject to the loss or restriction of controlled substances privileges and discipline by the appropriate professional state licensing board.

This booklet will help you meet these responsibilities and legal requirements. It summarizes key aspects of Missouri and federal controlled substance law and outlines common sense procedures that practitioners can use to prevent diversion of these drugs.

Additional educational handouts and publications regarding record keeping, forms and preventing prescription fraud are available at the website of the Bureau of Narcotics and Dangerous Drugs at www.dhss.mo.gov/BNDD.

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How This Booklet is Planned Out—Chronologically:

This booklet is laid out in chronological order. We first define controlled substances so practitioners can learn what they are and where to find a list. Next we talk about having proper state and federal controlled substances registrations. Then we purchase, store them securely, administer, dispense, provide proper packaging, required labeling and then the required record keeping such as receipt records, inventories, dispensing logs and documentation in patients' charts. How to dispose of unwanted controlled substances is covered. The booklet provides a lot of information on the requirements for prescribing, what the limits are, what must be documented and how prescriptions may be transmitted.

This book is compiled of the most frequently asked questions from practitioners and items they wish to cover during educational presentations. Not every single law and circumstance can be covered in this booklet. The website of the DEA given below and the website of the BNDD given on page two have links to many more educational handouts, as well as state licensing boards whose websites may be viewed at www.pr.mo.gov.

What Are Controlled Substances ?

A controlled substance is a drug or other substance that comes under the jurisdiction of the Federal Controlled Substances Act of 1970. Narcotics, depressants, stimulants, hallucinogens and anabolic steroids are regulated by the Controlled Substances Act (CSA) and are listed in one of five schedules.

Schedule I substances have a high potential for abuse and no accepted medical use in the U.S. Schedule II drugs also have a high abuse potential with a severe liability for psychic or physical dependence, but in general are substances that are approved by the FDA for a therapeutic use. Schedules III-V includes drugs with decreasing levels of abuse potential. Schedule IV drugs are predominantly benzodiazepines.

In the state of Missouri, the Comprehensive Drug Control Act of 1989, administered by the Bureau of Narcotics and Dangerous Drugs in the Missouri Department of Health and Senior Services, closely parallels federal law. The statutes are in Chapter 195 RSMo and the state regulations are in 19 CSR 30-1.00 through 1.078. In some instances, however, Missouri's law is more stringent and takes precedence over federal law. For example, in Missouri, narcotic-containing cough syrups and certain products that contain ephedrine are listed in Schedule IV and cannot be purchased without a prescription. In Missouri, drug products containing solid dosage forms of pseudoephedrine are Schedule V and must be signed for at the pharmacy counter. Legend drugs with pseudoephedrine that require prescriptions are not Schedule V.

A List of Controlled Substances:

You may find a list of controlled substances in Missouri Statutes in Section 195.017, RSMo. These are listed by Schedule.

For a more user-friendly listing of controlled substances, you may view a searchable listing of controlled substances at the DEA's website, www.deadiversion.usdoj.gov . The left side of their homepage has a link where you can see all controlled substances in alphabetical order or you may also search them by schedule. It also matches brand name drug products to generic names.

Controlled Substance Registrations

For an individual practitioner to conduct any activities with controlled substances in Missouri, they must obtain registrations from both the Missouri Bureau of Narcotics and Dangerous Drugs (BNDD) first, and secondly the federal Drug Enforcement Administration (DEA). Individual practitioners include physicians, dentists, optometrists, podiatrists, veterinarians, and advance practice nurses. Practice sites such as offices and clinics are not registered separately from individual practitioners.

A full BNDD registration and a DEA registration must each be obtained every three years. The BNDD registration terminates if a practitioner discontinues practice at their registered location without proper notification to the BNDD. If this occurs, the practitioner no longer has controlled substance authority. If the BNDD is notified in writing, within 30 days of a change of practice location, then their registration may be amended.

A full 3-year registration is given at a Missouri practice location where patient care occurs and controlled substance activities take place. This is the practitioner's principal practice location where they spend the most time. This is where patients' records are kept and this location is open for inspection.

A temporary or *locum tenen* registration is issued for a one-year period. This registration is for travelling practitioners who fill in on a temporary basis. These practitioners must provide a Missouri practice location of where they will spend the majority of their time in Missouri. They may provide a separate mailing address to their home or employment agency. These practitioners are not allowed to accept or stock controlled substances for dispensing. These practitioners must maintain a log that lists all of their Missouri practice locations and the dates they worked there. This log must be maintained for two years and made available upon request.

A veterinarian may work under the authority of their employer's DEA registration. However each and every individual veterinarian must have their own personal Missouri state registration in order to conduct controlled substance activities in Missouri. A veterinarian who practices under their employer's DEA number cannot issue controlled substance prescriptions. An individual DEA number is required to issue a controlled substance prescription.

Physicians in residencies and training programs may use the hospital's DEA number with a suffix that identifies them. These practitioners are limited to only using controlled substances on the patients of the hospitals and facilities they are training in.

Do I Need Multiple Registrations?

Most practitioners have only one registration. They can purchase, stock, administer, dispense and prescribe at their principal and registered location. They can travel all over Missouri and prescribe from any locations.

Additional registrations are required if you:

1. Begin stocking and storing controlled substances at more than one location. There must be a separate location at every separate location drugs are stored;
2. Perform other activities other than being a practitioner, such as becoming a manufacturer, distributor, researcher, analytical lab, importer or exporter.

Any questions regarding registrations should be directed to the BNDD at (573) 751-6321

Purchasing/Obtaining Controlled Substances:

When practitioners want controlled substances for administration and dispensing in their offices, the practitioners may only have controlled substances transferred to them by another authorized DEA registrant and proper transfer records of documentation must be maintained. There are strict requirements for what a stocking practitioner must do and there are specific laws about what practitioners cannot do to obtain controlled substances.

What you may do:

1. Purchase and obtain controlled substances from a pharmacy, wholesaler, distributor, or have drugs transferred to you by another DEA registrant. You should call the other registrant and share required information for documenting the drug transfer such the name, addresses and DEA numbers of the supplier and the receiver. A transfer form template is provided in the forms section of this booklet.

What you may never do:

1. No practitioner may issue a prescription to obtain office stock. Prescriptions are for patients only and must have a patient name. Never write a prescription for office stock. It is prohibited by law.
2. No practitioner may accept any portion of a patient's controlled substance prescription for any reason, unless you were the original practitioner who initially dispensed the drugs. This is by statute 195.070.4, RSMo. If you dispensed drugs and the patient wants to return them, then you can take them back for destruction. If you were not the dispenser and the drugs came from a pharmacy or other practitioner, you may not take possession of the drugs.
3. Never store patients' controlled drugs for them in your practice.
4. Never store unused medications and use them for dispensing to other patients.

Continuous Record Keeping For Accountability

Controlled substances are documented and tracked from the day they are made until they are dispensed into the hands of a patient. Every time the drugs change hands there must be a documented paper trail.

Drugs are tracked from the manufacturer, to the distributor, then to the pharmacy or to the practitioner. Records must be maintained of the drug names, strengths, dosage forms and quantities you received and the dates you received them. You must also document the names, addresses and DEA numbers of other registrants you transfer with.

It is just like balancing a bank book. You must be able to document and account for every dosage unit you have received. Every dosage unit you have administered or dispensed. You must be able to know what balance you should have on hand so that if any are missing it can be reported immediately.

As we go through activities with controlled substances in your practice we will cover the following types of record keeping requirements

1. Purchasing/Receipt Records
2. Initial Inventory
3. Annual Inventory
4. Transferring Drugs Out
5. Administration/Dispensing logs
6. Prescription documentation
7. Faxing prescriptions
8. Disposal of unwanted drugs
9. Reporting losses
10. How to audit

Controlled Substance Receipt Records

Registrants must maintain a record of all controlled substances they receive. The receipt records must contain the following information:

- Name, address and DEA number of the supplier;
- Name, address and DEA number of the recipient;
- Drug name, strength, form and quantities received;
- The date the drugs were received.

All of this information must be maintained on file by the registrant and made available for inspection and copying. There are no exceptions for samples. All controlled substances must have records maintained.

Caution: If you choose to use a packing slip, invoice or billing record as your receipt record, you are responsible to make sure all of the information required above is documented on the records you maintain.

When you want to receive Schedule II drugs, you will execute a DEA Form 222 Order Form.
When you want to receive drugs in Schedule III—V, you may create a form or record of your own and no specific form is required. The record you create must have all of the required information. A transfer form template is included in the forms section of this booklet.

Receiving Schedule II Drugs Requires DEA Forms:

All transfers of Schedule II controlled substances between registrants require a DEA Form 222 Official Order Form. You may obtain these order forms from the DEA at www.deadiversion.usdoj.gov They should be secured and any lost 222 forms must be reported to the DEA immediately.

The registrant who is requesting the drugs starts the process. The purchaser fills out the form which has their name, address and DEA number. They list the drug name, strength, form and quantities desired. The name, address and DEA number of the supplier/distributor is documented. The form is sent to the supplier. The purchaser keeps the 3rd copy as a receipt record.

The supplier will receive the written form requesting the drugs. The order will be filled and shipped back to the purchaser. The purchaser must document their 3rd copy of the form to document what quantities they received and the dates of receipt. These forms must be maintained for two years.

Only the registrant whose name appears on the forms may sign and execute these order forms. If the registrant wishes to delegate the signing of these forms to another person, they may do so, however they must execute a power of attorney form. Power of attorney forms are available on the website of the BNDD at www.dhss.mo.gov/BNDD.

Receiving Schedule III—V Drugs

You are required to maintain a receipt record with all of the information listed above. There is a transfer form you may use included in this booklet or you may create your own. You are responsible to make sure it is compliant. It is to your advantage to use the included form. If you document the form completely, both the supplier and receiver should keep a copy. It works as a "receipt" record for the receiver and then a "transfer out" record for the supplier.

Storage of Controlled Substances

Individual practitioners must store controlled substances in a securely locked, substantially constructed cabinet or safe. Access to the storage area should be restricted to persons specifically authorized to handle the controlled substances. This includes restricting the number and accessibility of keys or passwords.

The safe or cabinet should remain locked at all times. It is not allowed to have it remain unlocked throughout the day while you are open for business.

If there are other practitioners in your building that have separate stocks of drugs then each practitioner must keep their individual drugs stored separately. Do not mix the drugs of multiple practitioners in one single safe or cabinet.

If the safe is small and portable it should be bolted to the floor or wall or placed in a locked closet.

Initial Inventory

On the very first day that you receive controlled substances for the first time, you must conduct an initial inventory on that day with your first arriving drug shipment. In case you want to perform an audit in the future to determine if drugs are missing, this initial audit would be your starting date and point in time. An initial inventory must document the following information:

- Registrant's name and DEA number;
- Date;
- Drug names, strengths, dosage forms and quantities;
- You must take the inventory at the opening or closing of business. You must document whether you took it at the opening or closing of business. You cannot take an inventory during business hours.
- If you have business that operates 24 hours, you must document the time of day;

There is a template form included with this booklet that may be used.

This initial inventory should be documented and filed away. Do not write on it again.

Schedule II drugs should be inventoried and documented separately from drugs in Schedule III—V. Do not include other non-controlled drugs or items on these inventories.

Annual Inventory

Once a year you must perform an annual inventory of controlled substances. This inventory should be performed exactly like the inventory described above. If you are undergoing a records inspection you should be able to produce an annual inventory that is less than 12 months old.

This annual inventory should be documented and filed away. Do not write on it again.

Schedule II drugs should be inventoried and documented separately from drugs in Schedule III—V. Do not include other non-controlled drugs or items on these inventories.

Administering and Dispensing Controlled Substances

Up to this point we have covered getting registered and purchasing and locking up the drugs. Now we get into the activities with drugs in the practice such as administering to a patient or dispensing drugs to a patient so they may leave your practice with drugs for future use. In this area we will cover record keeping, packaging, labeling and proper actions by staff.

Record Keeping—Administration/Dispensing Logs

Registrants must maintain a record of all controlled substances received, administered, dispensed, or otherwise disposed of. You must be able to document what patients have received drugs and how much and when. It is required that practitioners maintain a log of controlled substances administered and dispensed. You must document the date, patient name, patient address, drug name, strength, dosage form and quantity dispensed, and the name/initials of the person performing the dispensing. A dispensing log form is available on the BNDD website at www.dhss.mo.gov/BNDD.

This log must be filed separately from patients' charts. Although it is required to document all controlled drug activities in a patient's chart, the practitioner must also maintain this separate log.

A Valuable Security Tool

Keeping this perpetual log provides a good security device to your practice. You can review the log and see what patients are receiving your drugs and how many and how often. All of the numbers should add up correctly and balance. If the count is off then you know that a drug has been diverted or someone dispensed without making a record. The log is also used to let you know when to order additional supplies.

Packaging When Dispensing

When you dispense and give a patient a supply of drugs for future use, you must follow the same laws as a pharmacy. You must place the controlled substances in a child-proof container. Dispensing in envelopes or napkins or other devices violates the FDA's Poison Prevention Packaging Act of 1970. If you are dispensing samples, the FDA accepts the factory packaging for samples as being compliant containers. There is no need for you to place a factory sample into a child-proof bottle.

Required Labeling

When you dispense drugs you must apply required labeling to the packaging. You must provide a label that contains the following information:

- Name and address of the dispensing practitioner or pharmacy;
- Patient's name;
- If you're a pharmacy, name of the prescribing practitioner;
- If drugs are dispensed from a prescription by an advance practice nurse, the name of the collaborating physician must be documented;
- Drug name, strength, dosage form and quantity;
- Directions for administration;
- Date;
- If the prescriber is a veterinarian, the animal species and animal owner's name must be documented

The burden of proof is on a person to prove lawful possession of controlled drugs. If drugs are not labeled the person is subject to arrest. In the past, patients arrested wrongfully have sued practitioners for not labeling medications as required and causing the patients to undergo an embarrassing arrest.

Required Warning Label or Caution Label
When a controlled substance is dispensed, the dispenser must affix a label or sticker that warns and cautions the patient that it is illegal to transfer these controlled substances to another person. This can be part of the major label or it may be a separate sticker.

Direct Supervision
When a registrant wants to have an employee dispense a controlled substance from their stock, the registrant must be present to provide direct supervision.

The one exception is that a physician may have a registered nurse dispense from their stock when the physician is not present, if the registered nurse has a collaborative practice agreement with the nurse.

A practitioner must provide direct supervision to employees who assist in administering and dispensing. Controlled substances may be administered or dispensed from an individual practitioner's inventory by an authorized employee or agent when the practitioner is not present at the registered location **only** when—

(A) The administration or dispensing is authorized by the individual practitioner under a written agreement pursuant to an arrangement established and implemented in accordance with Missouri statutes;
(B) The person who administers or dispenses the controlled substance is authorized by statute to administer or dispense controlled substances;
(C) The person who administers or dispenses the controlled substance is registered with the Department of Health and Senior Services to administer or dispense controlled substances;
(D) The person who administers or dispenses the controlled substance does so in compliance with all provisions of Chapter 195, RSMo and regulations promulgated there under.

For Physicians
If you are a licensed physician you must also follow the regulations of the Missouri State Board of Registration for the Healing Arts. They have a non-pharmacy dispensing rule in State Regulation 20 CSR 2150-5.020 that includes the dispensing of all drugs and not just controlled substances.

Transferring Drugs Out to Another

There may be a time when you need to transfer some drugs to another registrant. You may want to send drugs back to a distributor or maybe transfer drugs to a fellow practitioner who is running low in supplies. You must document the movement of the drugs with a transfer form. If it is a Schedule II drug, the receiving registrant would send you a DEA Form 222 Order Form. If the drugs are in Schedules III—V the two of you must document a transfer form. A transfer form template is included in this booklet. The documentation must include the names, address and DEA numbers of the supplier and receiver, as well as the date and the drug names, strengths, forms and quantities received. This document serves as a transfer record for the supplier and a receipt record for the receiver.

It is the responsibility of the supplier to always insure the person they are transferring drugs to is a BNDD and DEA registrant. The state registration of an individual practitioner can be verified at the BNDD website of www.dhss.mo.gov/BNDD.

Disposing of Unwanted Controlled Substances

There will be times when a practitioner wants to dispose of unwanted controlled substances. There are laws regarding how practitioners may dispose of unwanted controlled substances. This booklet is prepared for individual practitioners so this booklet does not cover disposal in licensed hospitals and long-term care facilities.

As a practitioner you must first ask yourself a question. "Why do I want to dispose of these medications?" There are two answers:

A. The drugs have been contaminated by patient contact. It is a left-over injectable medicine in a syringe; or it was a tablet that fell out of a patient's hand or mouth. If this is the case, the drug may be destroyed by two employees in the practice. The drug must be destroyed beyond reclamation and documented as described below in the next section.

B. The drugs have not been contaminated but they are out-dated, expired, or simply no longer wanted. In this case the drugs must be transferred to another registrant and they may not be destroyed by the practitioner. You may send them back to the distributor who supplied them if they will accept them. You may send them to a reverse distributor, which is a company that collects unwanted medications for destruction. There is a list of these reverse distributors at the BNDD website www.dhss.mo.gov/BNDD.

Documenting Controlled Substance Destruction

If you are administering and dispensing controlled substances then you should already be maintaining an administration and dispensing log to show the use of all controlled substances. The wastage and destruction of controlled substances should be documented on this log to maintain an accurate balance.

The drug should be destroyed beyond reclamation. The destruction record should include the date, drug name, strength, form, and quantity destroyed. The reason for the destruction, the name person performing the destruction shall sign the log as well as the person witnessing the destruction.

How to Conduct an Audit of Controlled Substances

If you want to determine if any controlled substances are missing you must use all of your required records to conduct an audit. An example audit covering one year is shown below.

Annual inventory on 1-1-2008.....200 tablets
Drugs received 1-1-08 to 1-1-09.....1,000 tablets
Total You Are Responsible For 1,200 tablets

Tablets Administered/Dispensed 1-1-08 to 1-1-09.....850 tablets
Tablets destroyed because of contamination.....5 tablets
Tablets returned to being outdated.....100 tablets
Total Doses Leaving the Practice 955 tablets

1,200 tablets minus 955 tablets = 245 tablets that should be in your safe.

Now you can see why all the records and dates are important.

Reporting Losses/Thefts of Controlled Substances

Registrants should always be able to tell if they have lost any controlled substances. They should have records in place so that an audit can be performed to determine if any drugs are missing. When reviewing the regulations, there are two types of losses described.

Insignificant Loss:
The drugs were not really "lost" and there was not crime or loss of accountability. This is when a compounding pharmacy has some liquid that sticks to the inside of a beaker or there is an insignificant amount of drug lost during a mixture or preparation. There was no theft or diversion. A tablet was dropped on the floor, stepped on and crushed and could not be picked up. When this happens, the drug was not truly "lost" because you know what happened to it. You must document this and what happened and it must be stapled to your annual inventory.

Lost or Stolen Controlled Substances:
These are cases where controlled substances were stolen, diverted or lost. This would include cases where drugs are missing and you are not sure where they went. These must be reported to the BNDD immediately upon discovery. You must submit a loss report form within 7 days. You must also submit a written loss report to the DEA. This is a DEA Form 106 for reporting lost or stolen drugs and you can obtain one at the DEA's website www.deadiversion.usdoj.gov

The BNDD state loss/theft report form is included in this website and may be obtained at the BNDD website www.dhss.mo.gov/BNDD.

Documentation Required on Written Prescriptions

State and federal law requires that a prescription must have all of the information required documented on the face of the prescription in order for the prescription to be legal. Federal law states that both the prescriber and the pharmacy have a corresponding liability to make sure the information is documented. Both the prescriber and the pharmacy are liable. The following information is required for controlled substance purposes:

- The date the prescription was signed and issued;
- Patient's name and address;
- Name, address and DEA number of the prescriber;
- Drug name, strength, dosage form, quantity to be dispensed;
- Directions for administration or use;
- Signature of the prescriber- original ink if patient presents prescription at the pharmacy.
- If the prescription is for greater than a 30-day supply of a Schedule II drug, the prescriber must write the medical reason on the prescription. A diagnosis code number is not acceptable.
- If the practitioner does not want the prescription filled until a certain date the prescriber may write "Do not fill until _____" at the bottom of the prescription.

Prescriptions Transmitted Verbally by Telephone

Prescriptions for Schedules III—V may be telephoned to a pharmacy. All of the information listed above is still required. The pharmacist must reduce it in writing and document the name of the person making the call and pharmacy employee receiving the call. Schedule II prescriptions may only be phoned in for emergencies where no other medical care is available. The prescriber must provide the pharmacy with an original prescription within 7 days. If no original prescription is presented as required, the pharmacy is mandated to report the prescriber to BNDD by law.

Faxing Controlled Substance Prescriptions

A prescription may be transmitted by fax machine, however the document faxed must be a facsimile of a completely documented prescription that contains all of the required information. The prescription should be prepared with all of the required information. The practitioner must sign it as required and then it may be faxed only after the prescriber has signed. It may not be printed by another person and it may not be stamped and it may not say, "signature on file."

The majority of all faxed controlled substance prescriptions are for Schedules III, IV and V.

There are limitations for Schedule II prescriptions when sent by fax:

- Although a prescriber may fax a Schedule II prescription so the pharmacy can get it ready, the pharmacy cannot dispense it until the patient presents the original prescription.
- The pharmacy may dispense a Schedule II prescription based solely on the faxed prescription under three conditions:
  1. The patient is in a long-term care facility and prescription documents that fact;
  2. The patient is in a hospice program and the prescription documents that fact;
  3. The prescription is for a narcotic preparation to be administered by infusion, meaning parenteral, intravenous, intramuscular, subcutaneous or intra-spinal.

Prescribers File Faxed Prescriptions Separately

After the practitioner has signed the prescription, it may be faxed. After the prescription has been faxed, the person faxing the prescription should sign and date it to document it has been faxed. The faxed prescription must be placed in a separate file where all faxed controlled substance prescriptions are maintained in chronological order.

Although controlled substance prescriptions get documented in patients' charts, the prescriber must maintain a separate chronological file of faxed controlled prescriptions. This file of faxed prescriptions must be separate from patients' charts.

Electronic Prescribing Not Allowed

Although the DEA has published a proposed rule, the DEA has not authorized the electronic transmission of controlled substance prescriptions as of this date. Prescribers may not use a computer to send a controlled substance prescription to a pharmacy. Although a computer may be used to prepare a prescription, the prescriber must print it and sign it before it can be faxed. Prescriptions with digital signatures or messages saying "signature on file" are not allowed at this time.

Multiple Schedule II Prescriptions

A practitioner may issue multiple prescriptions for Schedule II drugs on the same date. All prescriptions should be dated at the top on the date they signed and issued the prescriptions. Each prescription should have "Do not fill until _____" across the bottom. Although multiple prescriptions can be issued at once, the prescriber cannot exceed a 90-day supply of Schedule II drugs.

CHART OF PRESCRIBING LIMITATIONS

Prescription Characteristic	Limitation Schedule II	Limitation Schedule III and IV	Limitation Schedule V
Mode of issuing prescription	Written mostly; Verbal in emergency; Faxed if injectable, or long term care or hospice	May be written or verbal or faxed	May be written or verbal or faxed
Refills	No Refills Allowed; Partial filling allowed for terminal patients or patients in long-term care facilities	Maximum of five within six months of issuing prescription	As authorized by the physician. Can be refilled PRN as prescriber allows for one year
Length of prescription validity	Six months	Six months	One year
Quantity limitations	30 days for most; Rx for over 30 days requires medical reason; Maximum is 90 day supply Can write multiple & separate Rx with "Do Not fill until date" written on bottom. Can't exceed 90 day supply	90 days	90 days

What Constitutes a Legal & Legitimate Prescription

Federal and state regulations specify legitimate purposes for prescribing controlled substances:

- A prescription for a controlled substance is valid only if it is issued for a legitimate medical purpose by a practitioner acting in the usual course of their professional practice.

  Three criteria should be met:
  1. The patient must desire treatment for a legitimate illness or condition.
  2. A practitioner must establish a legitimate need through assessment, utilizing pertinent technical diagnostic modalities.
  3. There must be reasonable correlations between the drugs prescribed and the patient's legitimate needs.

- The Intractable Pain Act, passed in 1995, provides guidelines for the treatment of chronic, intractable pain. This law was intended to clarify the parameters for treating chronic pain with controlled substances. The physician must document the diagnosis and treatment of chronic pain in the patient record and the use of controlled substances must be therapeutic in nature and manner utilized. Physicians may not prescribe or dispense controlled substances to a patient for chemical dependency unrelated to intractable pain or to a patient who the physician knows, or should know is using the medication in a non-therapeutic manner (unless they are approved and registered as a narcotic treatment program).

  Physicians may be subject to disciplinary action for nontherapeutic use of controlled substances, failing to keep accurate on-going treatment records, failing to keep complete and accurate controlled substance records, writing false or fictitious prescriptions, or prescribing controlled substances in a manner inconsistent with state or federal drug laws.

- Practitioners may not issue a prescription to obtain controlled substances for dispensing to patients. Practitioners can purchase controlled substance medications for stock from a drug distributor or pharmacy. A DEA form 222 must be used to obtain Schedule II controlled drugs. Each practitioner must maintain documentation as required under state and federal laws.

- Controlled drugs for a practitioner's personal treatment must be prescribed by another appropriate practitioner, under the basis of an established practitioner/patient relationship. Practitioners are prohibited by law from prescribing or dispensing controlled drugs for their personal use except in a true medical emergency.

- It is recommended that practitioners do not prescribe, dispense or administer controlled drugs to office staff or family members. If the physician does decide to treat family members or employees, the physician must do so under the auspices of a legitimate patient/physician relationship and in "good faith". This includes performing a proper evaluation, maintaining a chart, listing a diagnosis, plan of treatment and prognosis, and using the same documentation and care as with regular patients.

- For dentists, veterinarians, podiatrists and optometrists certified to use therapeutic pharmaceutical agents licensed by their respective professional boards, the prescribing, administering, dispensing or distribution of controlled substances is limited to the scope of their respective professional practice after establishment of a practitioner/patient

relationship. If the practitioner does prescribe, dispense or administer to office staff or family members, these individuals must be treated in the same manner as regular patients. This includes maintaining a chart, listing a diagnosis, plan of treatment and prognosis, and using the same documentation and care as with regular patients.

- "Internet Prescribing" – The Internet is primarily a communications tool that can be used to facilitate any type of business. The DEA issued a notice on April 27, 2001 in the Federal Register in reference to practitioners using the Internet as part of their business.

  Some practitioners prescribe medications based on an on-line Questionnaire. Federal law requires that "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice" (21 CFR 1306.04(a)). Every state separately imposes the same requirement under its laws. Under Federal and state law, for a practitioner to be acting in the usual course of professional practice, there must be a bona fide practitioner/patient relationship.

  For purposes of state law, many state authorities, with the endorsement of medical societies, consider the existence of the following four elements as an indication that a legitimate practitioner/patient relationship has been established:

  - A patient has a medical complaint;
  - A medical history has been taken;
  - A **physical examination** has been performed; and
  - A legitimate clinical relationship exists between the medical complaint, the medical history, the physical examination, and the drug prescribed.

  Completing a questionnaire that is then reviewed by a practitioner hired by an Internet pharmacy can not be considered the basis for a practitioner/patient relationship. A consumer can more easily provide false information in a questionnaire than in a face-to-face meeting with a practitioner. It is illegal to receive a prescription for a controlled substance without the establishment of a legitimate practitioner/patient relationship, and it is unlikely for such a relationship to be formed through Internet correspondence alone.

Required Documentation in Patients' Charts

All controlled substance activities are required to be documented in patients' charts. The controlled drug records in patients' charts are open for inspection and copying by BNDD and as all controlled drug records must be produced within 3 days upon request. All administrations, dispensing, prescriptions and refills must be documented with the date, drug, strength, form, quantities and refills.

Not having a chart not only violates the record keeping law but is consider failure to establish a legitimate practitioner-patient relationship and it is prescribing/administering/dispensing in the absence of good faith.

It is also a security violation. If prescriptions are not charted then practitioners would not know if a refill request was timely.

How to Prevent Diversion in Your Practice

Adherence to state and federal regulations goes a long way in protecting your practice from becoming a source of drug diversion and prescription drug abuse. The best practice is to have set policies and procedures and train your staff to follow them. The practitioner must provide supervision to see that the policies are enforced. Although many practitioners know laws and good practices they sometimes become too busy to supervise staff.

Suggestions for Practitioners on How to Protect their Practice and Patients:

1. Keep all prescription pads secure and not left out where people may obtain them to forge prescriptions.
2. Only the registered practitioner should be allowed to call in or place orders for new stocks of controlled substances.
3. If the practitioner is too busy and ordering new stock is delegated, only one employee should have the right to place orders. Do not let all staff members place orders.
4. When controlled drugs arrive in the practice, they should be opened, checked in, and added to inventory by at least two licensed professionals. Do not let one person do this alone. Do not let the same two people do it all the time.
5. The person who pays the bills should not be allowed to order drugs. The person who orders drugs should not be allowed to write checks. This prevents someone from ordering drugs and paying the bill without the practitioner's knowledge. The person who orders the drugs should communicate with the person who verifies what drugs the practice received. The receipt invoice should be given to a separate employee who pays the bills. **The receipt for drugs and bills should be reviewed by the practitioner.**
6. Only certain staff should be allowed to call in telephoned prescriptions to area pharmacies. The practitioner's staff may wish to designate a special "code word" or "secret password" with the pharmacy so the pharmacy knows the call is valid.
7. Use your continuing administration log as a perpetual inventory so you know how many dosage units have been dispensed and how many you have left on a daily basis.
8. As a practitioner, review the administration log to make sure you recognize the patient names and that no fictitious patient has been invented.
9. Only licensed professionals should have access to the locked drug cabinets.
10. Periodically, ask a local pharmacy for a print out of all the controlled substance prescriptions they have filled, that you issued. Look at the print out and make sure you recognize the names as your patients. Follow up on any names that seem strange or unfamiliar.
11. Set up a rotating self-inspection where on a monthly basis, the office manager or practitioner inspects the practice. Check the current stocks to make sure they are locked. Review the inventory and current balance. Review what has been ordered. Review what bills have been paid. Look at the administration log to make sure all the required information is recorded.
12. Make sure your controlled substances are inventoried at least once a year and recorded in your files. An inventory is required annually.
13. Set up a policy of random drug testing for employees.
14. If a practitioner chooses to treat their own family members or staff, they must keep charts and records on their family and staff just like any other patient. Allowing staff to take office medications on the job may lead to serious violations.
15. Before hiring a new employee, conduct an extensive background check by reviewing licensure discipline and running a criminal history check. Before employing any person with a criminal conviction for a drug offense who has access to controlled substances, the employer must first obtain a waiver. Drug related misdemeanors require a waiver from the BNDD and drug related felonies require a waiver from both the BNDD and the DEA.

Preventing Prescription Fraud & Drug Seeking Patients

Our Task Force could dedicate an entire booklet to scams, schemes and tricks of professional patients and also provide practitioners on how to prevent them. In fact, we did just that. Rather than providing all of that information here, we invite you to visit the BNDD website at www.dhss.mo.gov/BNDD and under the link of publications, click on our booklet regarding Preventing Prescription Fraud. This booklet provides over twenty scams that professional patients use. It also provides practitioners with tips on how to deal with these patients, report fraud and what information they can share without violating confidentiality and HIPAA.

Helpful Websites - Controlled Substance Information

BNDD.....www.dhss.mo.gov/BNDD

DEA..... www.deadiversion.usdoj.gov

State Boards.....To view the website of licensing boards in the Division of Professional Registration, visit the website at www.pr.mo.gov and then click on the licensing board of your choice. Many boards have their own educational materials and newsletters.

Caution

The purpose of this information is to educate and inform the practitioner of the regulations and statutes pertaining to controlled substances and make recommendations to assist the practitioner in protecting their practice and patients from diversion, drug abuse and misuse. It is not the intent to reduce or deny the use of controlled substances where medically indicated. Nothing in this booklet shall be construed as authorizing or permitting any person to do any act that is not authorized or permitted under federal or state laws. In addition, none of the policy and information in this booklet may be construed as authorizing or permitting any person to do any act that is not authorized, or refuse to meet any requirements imposed under the regulations published in the most recent publication of the Code of State Regulations or the Revised Statutes of Missouri.

ANNUAL INVENTORY OF CONTROLLED SUBSTANCES

Date: ______________ Schedule(s):________________
(Schedule II must a separate form than III—V)

Opening or Closing of Business, or Time of Day:__________________

Inventory Performed By:____

DRUG NAME	FORM (tab/cap/inj)	STRENGTH mg/ml	QUANTITY

TRANSFER OF CONTROLLED SUBSTANCES

Schedules III, IV, & V only

_____

Date of transfer

Receiving Registrant's Information

Name:_____

Address:_____

_____

_____

DEA #:_____

BNDD#:_____

Supplying Registrant's Information

Name:_____

Address:_____

_____

_____

DEA#:_____

BNDD#:_____

DRUG NAME	STRENGTH	DOSAGE FORM	QUANTITY OF DOSAGE UNITS	COMMENTS

_____

Signature of Receiver

_____

Signature of Supplier